Asthma and Allergy Foundation of America

AAFA Comments to FDA Allergenic Products Advisory Committee
January 21, 2016

Good afternoon.

My name is Cary Sennett, and I am President and CEO of the Asthma and Allergy Foundation of America, AAFA. I thank you for the opportunity to bring AAFA's perspective, and the perspective of the more than 60 million Americans with asthma and allergic disease, to the Committee's deliberations.

In my brief remarks today, I would like to introduce AAFA, and the patient's perspective on allergic disease, to the Committee. I will then focus on what we believe are the issues that the Committee must consider. Finally, I will close with what I hope is a clear offer to provide help to the Committee, as its work moves forward.

AAFA is a not-for-profit organization working to improve the lives of people with asthma and allergic disease. We believe that the patient's voice is a critical input, as we strive to create a healthcare system that is centered on the needs and values of patients, and hope to bring the patient's voice to conversations like the one we are having today.

What is it like to have food allergy, or allergic rhinitis, or asthma?

Food allergy means a life of constant—unremitting—vigilance:

- living with the reality that your next meal—or your child's next meal—could be her last
- living with the reality that a bully at school—or even a friend at a birthday party—could threaten your child with something as simple as a peanut butter and jelly sandwich.

The symptoms of allergic rhinitis and asthma limit life profoundly. Remember the misery of the worst cold you've ever had. What if it lasted for three months? And what if it happened twice a year? This is the reality for millions of allergy sufferers who may be—as the Committee clearly appreciates—at risk to "march on" to develop asthma. This condition not only limits quality of life; the CDC estimates that asthma kills nearly 10 Americans every day

What do patients want? They want treatments that are safe and effective—although I should point out that a study that we did, with collaborators at the Universities of Pittsburgh and Michigan (published in the Annals of Allergy, Asthma and Immunology in 2012)[1] suggests that families participating in food allergy oral immunotherapy were surprisingly willing to begin that therapy, without evidence that OIT was safe and effective. I think this

[1] Traister RS, Green TD, Mitchell L, and Greenhawt M. Community opinions regarding oral immunotherapy for food allergies. Ann Allergy Immunol 109(2012): 319-323.

speaks to the sense of desperation that is prevalent in the food allergy community—and the importance of the work that the Committee is considering.

We believe that the risk of life-threatening anaphylaxis related to food allergy requires that safety of food allergy immunotherapy products be assessed in a double-blinded and highly controlled environment.

We believe that evaluation of effectiveness should include metrics that reflect the issues that are important to patients—symptom control, quality of life, and functional status. And that endpoints need to be meaningful not only to statisticians, but to patients.

Finally, we believe that "effectiveness" has to mean "it works in the real world;" this is especially true for therapies directed at aero-allergens/patients with allergic rhinitis. From a patient's perspective, the important questions are:

- Is this therapy better than what I have now? And
- Will this therapy make me feel better, in the environment in which I live, work and play?

I want to take just a moment to make sure that I remind the Committee, and the FDA, that—important as your work and new therapies are—there remain significant opportunities to improve the lives of people with asthma and allergic disease by finding ways to make the therapies that we have more available and more effective for those who will benefit from them. This may be a topic for another day (and another meeting), but—because it is so important—I feel the need to call it out today.

Finally, we appreciate the opportunity to share our thoughts today. But I want to close by making it clear that AAFA is willing—and may be able—to assist the Committee and the FDA to move the work of evaluating allergenic products forward.

In particular, AAFA has the ability to bring the voices of families with food allergy, and, increasingly, individuals with other allergic diseases, to evaluation work, through the online communities that we support. And we have the opportunity to assist the Committee and the FDA, to build expertise in the patient community, through work that the Patient Centered Outcomes Research Institute (PCORI) is supporting. Finally, we are ready to partner with the Committee, the FDA, and any number of others, who recognize as we do the opportunity not only to advance the basic and clinical science related to immunotherapy, but to advance our collective efforts to implement the science that we have, more consistently and more effectively.

Thank you!